

Application Ser. No. 10/522,215
Amendment and Response

Attorney Docket No. 65321(54558)

RECEIVED
CENTRAL FAX CENTER

FEB 28 2007

REMARKS

Claims 28-59 were pending in the application, with claims 38-40 and 42 withdrawn from consideration. Claims 31 and 51 have been cancelled without prejudice or disclaimer and claims 28, 32, and 48 have been amended. Accordingly, claims 28-30, 32-50, and 52-59 will be pending in the application upon entry of the amendments presented herein.

Amendment and cancellation of the claims herein are not to be construed as an acquiescence to any rejections set forth in the instant Office Action or in any previous Office Action and were done solely to expedite prosecution of the application. Applicant reserves the right to pursue the subject matter of the original claims in this or one or more subsequent patent applications.

Priority Claim Under 35 USC § 119 (a)-(d) or (f)

Applicant notes with appreciation the acknowledgement of the priority claim of the instant application in item 12 on page 1 of the Office Action. Page 1 of the specification has been amended to recite the priority claim and related application information.

Support For Claim Amendments

Claims 28 and 48 have been amended to recite a solid cancer or haematological malignancy that comprises a "membrane androgen receptor (mAR)". Support for the amendment can be found in the specification, for instance, on p. 13, lines 16-21 and p. 14, lines 3-19 (generally disclosing membrane steroid receptors (a class encompassing mARs) as targets for drug intervention). Further support can be found at p. 17, line 14 to p. 20, line 19 (disclosing generally applicable methods for detecting mARs in cultured cells using flow cytometry, confocal laser microscopy, and paraffin sectioning). See also: p. 24, line 6 to p. 27 (showing expression of mAR in cell lines (LnCap cells) and prostate cancer samples); p. 27, line 21 to p. 31, line 5 (showing mAR expression in cells associated with various hematological malignancies such as leukemic cells, lymphocytes, monocytes, polymorphonuclear cells); and Figures 1-6 (showing, among other things, binding and selectivity characteristics of membrane androgen receptor in LNCap cells, benign prostate hyperplasia (BPH) tumor cells, and peritumoral non-tumor cells).

Application Ser. No. 10/522,215
Amendment and Response

Attorney Docket No. 65321(54558)

Claim 32 has been amended and claims 28 and 48 have been further amended to feature "androgen" steroid. Support can be found, for instance, in the language of claims 31 and 51 (both now cancelled). The claims have been further amended to recite "mammalian" protein as part of the androgen steroid composition to be administered in the method. Support can be found in the specification, for example, at p. 11, last line.

No new matter has been added.

**Rejection of Claims 28-33, 35-37, 41, 43-53, and 55-59 under
35 U.S.C. § 112, First Paragraph (Written Description)**

Claims 28-33, 35-37, 41, 43-53, and 55-59 are rejected under 35 U.S.C. § 112, first paragraph, as lacking written description. In particular, the Office Action sets forth the allegation that the claimed methods reference "any proliferative disorder that could be characterized as a 'solid cancer' or 'haematological malignancy' and that "attempts to treat cancer frequently lead to 'unpredictable' outcomes. Action at p. 3. In support of this position, six (6) scientific papers were referenced on p. 4 of the Action. Applicant respectfully disagrees and traverses the rejection.

However, without acquiescing to the rejection and in order to expedite prosecution of the application, Applicant has amended claims 28 and 48 (from which the other claims depend) to recite that the solid cancer or haematological malignancy include a *membrane androgen receptor (mAR)*. As is clearly evident from Applicant's specification, the claimed methods can be used to treat solid cancers and haematological malignancies that include the mAR. See, for instance, pp. 32-33 and Figure 9 (showing, among other things, that the prostate cancer cell line LNCaP, when implanted into nude mice, can be treated using the invention method).

At p. 4 of the Action, the Office asserts that the data Applicant presented as Figure 9 are "highly suspect" on grounds that the tumor used was not identified. Applicant respectfully disagrees for at least the following reasons.

As the specification makes clear at, for instance, p. 23, line 19 to p. 24, line 2, nude mice were injected with the LNCaP cell line (a line derived from human prostate cancer) diluted in Matrigel. Tumors were measured (+/- drug) until four weeks of treatment. Specification at p. 23. The data provides clear evidence that the claimed method works in an animal model of human cancer.

Application Ser. No. 10/522,215
Amendment and Response

Attorney Docket No. 65321(54558)

Applicant notes that related mouse experiments were published in peer-reviewed scientific journals well after the filing date of the instant application. See, for example, A. Hatzoglou, *et al.* (2005) *J. Clinical Endocrinology* 90: 893-903, which is cited in the Supplemental Information Disclosure Statement filed concurrently herewith. According to Hatzoglou, *et al.*, a particular steroid androgen conjugate (testosterone-BSA) reduced LNCaP tumor size by 60% in nude mice. These results were not viewed as "highly suspect" but rather as being indicative of a method that can be used to treat cancer. Accordingly, the assertion that the results of Figure 9 of Applicant's specification is "highly suspect" is without scientific merit and should be withdrawn.

The Office asserted that "extrapolation from treatment of one form of cancer to other forms of cancer leads to "unpredictable" results. Action at p. 4. Applicant disagrees insofar as the statement concerns the presently claimed invention. Applicant's specification provides ample written description clearly showing that he had full possession of the claimed invention as of the filing date. See at least pp. 32-33 and Figure 9 showing that certain androgen steroid conjugates (testosterone-BSA) decreased LNCaP tumor cell proliferation *in vivo* and *in vivo*. Accordingly, Applicants have fully satisfied the statutory requirements of §112 (written description).

On pp. 5-6 of the Office Action, the claims were rejected on grounds that the claimed method used "any steroid" and conjugates with protein obtained from "plant, fungus, bacteria or reptile". Although Applicant disagrees with the stated grounds for rejecting the claims, Applicant believes that the present claim amendments address these concerns.

Accordingly, claims 28 and 48, and the claims depending therefrom, comply with the written description prong of §112 and Applicant respectfully requests reconsideration and withdrawal of the rejection.

Rejection of Claims 28-32, 34-47 under
35 U.S.C. § 112, First Paragraph (Written Description)

Claims 28-32, 34-47 are rejected under 35 U.S.C. § 112, first paragraph, as lacking written description. In particular, the Office Action sets forth the allegation that the claims encompass various plant proteins, fungal proteins, bacterial proteins, viral proteins, and reptilian proteins.

Application Ser. No. 10/522,215
Amendment and Response

Attorney Docket No. 65321(54558)

Applicant respectfully disagrees and traverses the rejection. Claim 44 and claims 45-47 depending therefrom are directed to administration of Testosterone3-(O-carboxymethyl)oxime-*human* serum albumin. Thus, these claims do not encompass various plant proteins, fungal proteins, bacterial proteins, viral proteins, and reptilian proteins.

Without acquiescing to the rejection of claim 28 and the claims depending therefrom and in order to expedite prosecution of the application, Applicant has amended claim 28 to recite *mammalian* protein. Applicant submits that the foregoing amendment addresses the basis for the rejection.

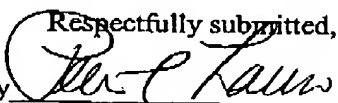
Accordingly, claims 28-32 and 34-47 comply with the written description prong of §112 and Applicant respectfully requests reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of all pending rejections and allowance of the application with claims 28-30, 32-50 and 52-59. If a telephone call with Applicant's representative would be helpful to expedite prosecution of the application, Applicant invites the Examiner to contact the undersigned at the telephone number listed below.

Applicant believes that no fees are required for consideration and entry of this Amendment and Response. However, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 65321(54558).

Dated: February 28, 2007

Respectfully submitted,
By 

Peter C. Lauro, Esq.
Registration No.: 32,360
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
617-517-5509
Attorneys/Agents For Applicant

Application No.: 10/522,215
Supplemental Information Disclosure Statement

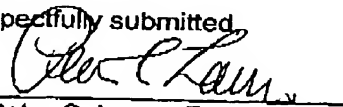
Docket No.: 65321(54558)

Applicant submits that this Supplemental Information Disclosure Statement is in compliance with 37 C.F.R. §1.98 and that no fees are required for its consideration and entry. However, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 65321(54558).

Dated: February 28, 2007

Respectfully submitted,

By



Peter C. Lauro, Esq.

Registration No.: 32,360

EDWARDS ANGELL PALMER & DODGE LLP

P.O. Box 55874

Boston, Massachusetts 02205

(617) 439-4444

Attorneys/Agents For Applicant